ABSTRACT

Objective: To evaluate the efficacy and safety of a new topical silicone gel for the early intervention in the management of scars. **Design:** In this 12-week, observational study, healthy subjects (n=15) with an accessible linear or hypertrophic scar were given the test product and instructed to apply twice daily. Subjects returned 14, 28, 56, and 84 days later for evaluation and recording of adverse events. **Setting:** Private practice of the author. **Participants:** Eligible subjects had a scar with a Vancouver Scar Scale total score ≥3 at baseline. **Measurements:** Improvement was evaluated by the Vancouver Scar Scale and Observer Scar Assessment Scale at baseline and at four follow-up visits. **Results:** The median total Vancouver Scar Scale score and median total Observer Scar Assessment Scale score decreased significantly from baseline at each visit, showing rapid and continuing improvement in the appearance of the scars. For Vancouver Scar Scale, significant differences of individual parameters from baseline began at 28 days for pliability and height, 56 days for vascularity, and 84 days for pigmentation. For Observer Scar Assessment Scale parameters, significant differences from baseline began at 14 days and continued until 84 days for

[Abstract continued on next page]

ORIGINAL RESEARCH

Efficacy and Safety of a Novel 100% Silicone Scar Gel Treatment for Early Intervention in Scar Management

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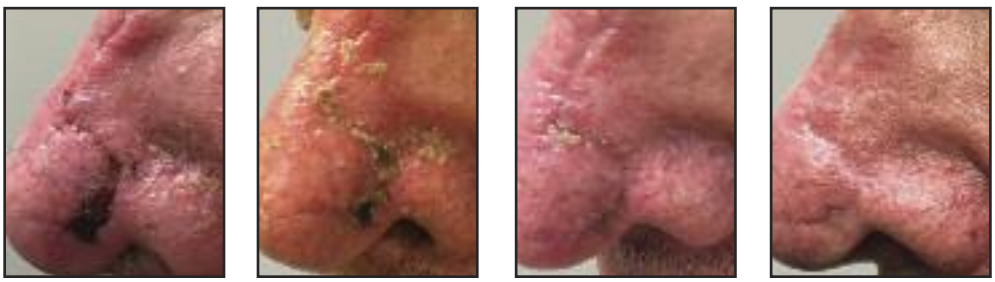

APPROXIMATELY 100 MILLION people in the developed world develop scars after certain types of surgery.[1] Scars are an undesirable yet normal outcome of wound healing.[2] Hypertrophic scars and keloids resulting from trauma, burns, and surgery can be associated with physical and psychological distress, and they can also be accompanied by significant pain and pruritus.[3]

Hypertrophic scars are defined as an excess of collagen in the dermis.[4] These scars are typically confined within the perimeter of the original wound and may regress over time.[2,5,6] Hypertrophic scars occur after 33 to 91 percent of burn injuries and after 39 to 68 percent of surgical procedures.[5] They are most commonly found in areas often under stretching tension, such as the shoulders, neck, knees, lower abdomen, presternum, and ankles.[2,7–9]

Several noninvasive and invasive options are currently available for the management and treatment of scars in patients who either experience trauma or undergo surgery. In the case of surgery, management of scars will typically start with careful attention to surgical techniques and best practices for wound care.[2,12] The extent of scar management applied to the wound will depend on the patient's risk of developing a scar as well as their level of concern about the scar's appearance. An algorithm for hypertrophic and keloid scar prevention and management

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[Abstract continued]

vascularization, thickness, and pigmentation. Pain and pruritis scores were low at each visit. Overall, 84.6 percent of subjects rated the treatment as excellent, very good, or good after three months of treatment. No adverse events were reported. **Conclusion:** The test product improved the appearance of scars after three months of twice-daily treatment and without adverse events.

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has been developed by an international advisory panel and was recently updated.[12]

According to this algorithm, silicone-based products are preferred and currently recommended as the first-line option for preventing and treating excessive scarring after surgery or trauma.[1,2,11,12] Indeed, silicone gel sheeting has been used effectively in scar management for more than 20 years. Nonetheless, the sheeting cannot be used near joints, on large anatomical areas, and on areas in which skin is difficult to cover due to its motility or contours. If the sheets are taped to the skin, patients often fail to comply, especially on unclothed areas. Patients must also wash the sheets regularly to prevent infection or rashes.[9,13]

Silicone gel has been studied extensively and shown to be as effective as silicone gel sheeting in managing abnormal scars without side effects.[13] For example, in a large 1,522-patient study, the twice-daily use of a silicone gel for a minimum of two months showed significant improvement in scar color, pliability, height, itching, and pain/tenderness in approximately 70 to 85 percent of patients. Both patients and physicians were highly satisfied with the ease of use, treatment duration, cosmetic outcome, and tolerability of silicone gel treatment.[14] When applied correctly silicone gel dries quickly and forms a nearly invisible sheet. Another advantage is that silicone gel can be applied over facial makeup to hide scars.[13]

Recently, a study by Shin et al[15]

Table 1. Visit schedule

PROCEDURE	VISIT 1 (SCREENING/ BASELINE)	VISIT 2 (DAY 14)	VISIT 3 (DAY 28)	VISIT 4 (DAY 56)	VISIT 5 (DAY 84, END OF TREATMENT)
Investigator VSS assessment	x	x	x	x	x
OSAS	x	x	x	x	x
Global subject satisfaction					x
Adverse events assessment	x	x	x	x	x
Standard photography of the scar	x	x	x	x	x
Distribution of study medication (60mg tube) and explanation of use	x	x (if needed)	x (if needed)	x (if needed)	

VSS = Vancouver Scar Scale; OSAS = Observer Scar Assessment Scale

suggested that early scar intervention, including the use of topical agents, was associated with decreased hypertrophic scar formation. The purpose of the present study was to evaluate the efficacy and safety of a novel topical 100% silicone gel for early intervention in scar management.

METHODS

In this 12-week, single-site, observational pilot study, subjects were eligible to participate if they presented with an accessible linear or hypertrophic scar with a total Vancouver Scar Scale (VSS) score ≥3 at baseline. Patients with a history of diabetes, allergy or sensitivity to any component of the test product, or collagen vascular disorder that would impact healing and wound repair were excluded from the study. Other exclusion criteria were pregnancy, nursing, and planned pregnancy during the study. Minor, major, or diffuse keloids and scars that spanned a joint or required the use of a pressure bandage were excluded.

The visit schedule is shown in Table 1. Informed consent, photography consent, inclusion/exclusion criteria, and screening questionnaire were obtained or completed during the first visit. Subjects were evaluated at five different time periods during the study. At Visit 1, the investigator evaluated the scar using the VSS[16] and the Observer Scar Assessment Scale (OSAS).[17] The VSS included vascularity (score 0–3), height (score 0–3), pliability (score 0–5), and pigmentation (score 0–2) while the OSAS scale included vascularization, thickness, and pigmentation (score 1–10 for each). Both the VSS and OSAS are widely used to assess scars[17,18] and have been validated.[17]

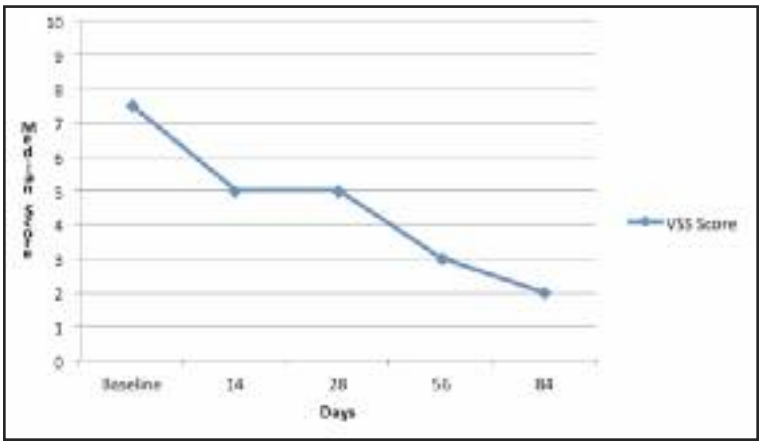

Figure 1. The median total Vancouver Scar Scale (VSS) score (n=14 for Days 0–56, n=13, for Day 84) at baseline and at each return visit. The reduction in VSS score compared to baseline was significant at 14 days (p=0.0015), 28 days (p=0.0034), 56 days (p=0.0002), and 84 days (p=0.0005).

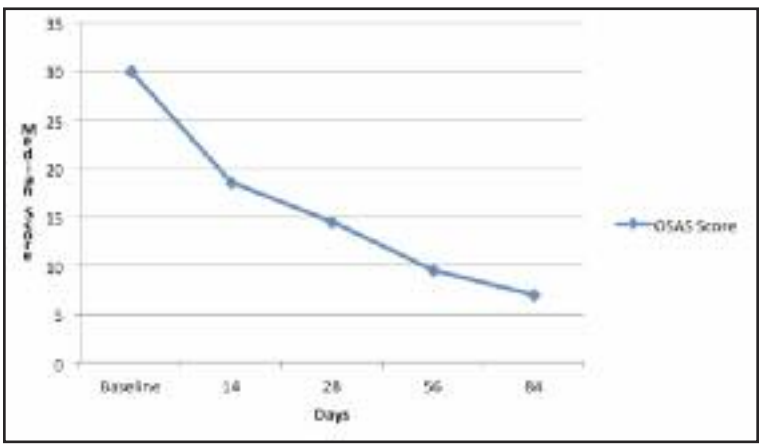

Figure 2. The median total Observer Scar Assessment Scale (OSAS) score (n=14 for Days 0–56, n=13, for Day 84) at baseline and at each return visit. The reduction in OSAS score compared to baseline was significant at 14 days (p=0.0012), 28 days (p=0.0009), 56 days (p=0.0002), and 84 days (p=0.0002).

Subjects were given a 20g pump of test product (Recedo™ Topical 100% Silicone Gel, Exeltis USA, Florham Park, New Jersey) and instructed to apply it twice daily, cleaning and drying the target area before each application. Subjects returned 14, 28, 56, and 84 days later for evaluation, photography, and recording of adverse events. Subjects were provided with additional product during the study if necessary. At the end of the study, subjects were asked to rate their satisfaction with the treatment as excellent, very good, good, moderate, or unsatisfactory.

The primary efficacy endpoint was the ability of the test product to

Table 2. Improvement in total VSS score (as % difference from baseline) at scar locations

SUBJECT NUMBER	SCAR LOCATION	VSS TOTAL SCORE		*DIFFERENCE (%)
		BASELINE	84 DAYS	
1	Nose	**36**	9 (56 days)**	75
2	Cheek	11	5	54
3	Cheek	39	11	72
4	Temple	40	7	82
5	Nose	39	5	87
6	Cheek	26	6	77
7	Nose	34	11	68
8	Cheek	26	10	62
9	Nose	35	7	80
10	Temple	35	8	77
11	Leg	21	5	76
12	Cheek	18	9	50
13	Cheek	10	9	10
14	Trunk	14	5	64
Median ± IQR				73.5±15.9

***(Baseline score – 84-day score) (100)/baseline score**
**** The 84-day data were not available.**
IQR = interquartile range, the difference between the 75th and 25th percentile

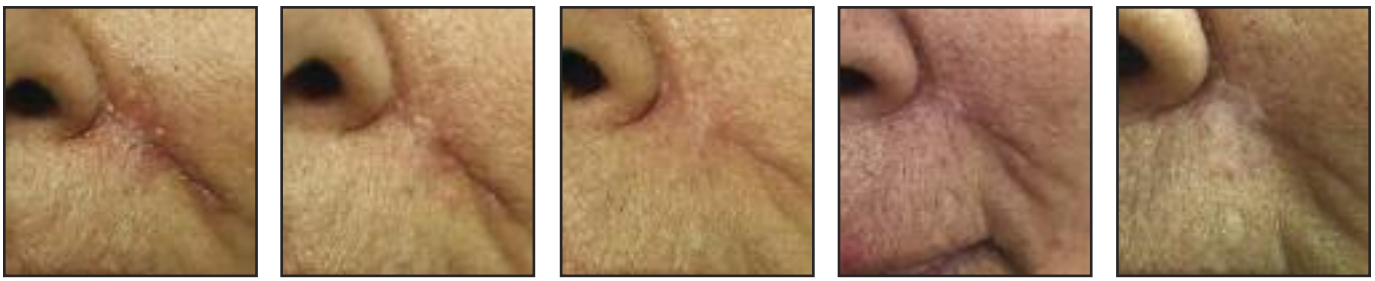

Figure 3. A linear scar below the frontal left cheek of a 75-year-old woman at baseline and at each return visit. The scar steadily improved until it is barely visible at 84 days.

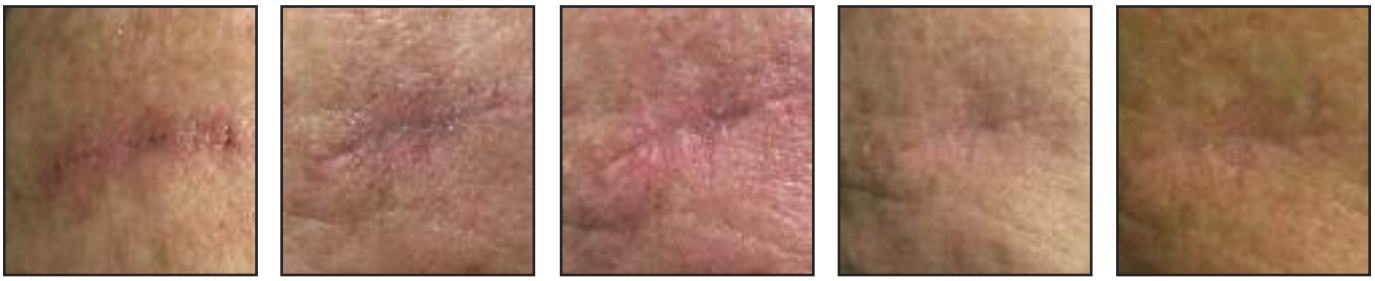

Figure 4. A linear scar of a 58-year-old man at baseline and at each return visit. The scar steadily improved until it is barely visible at 84 days.

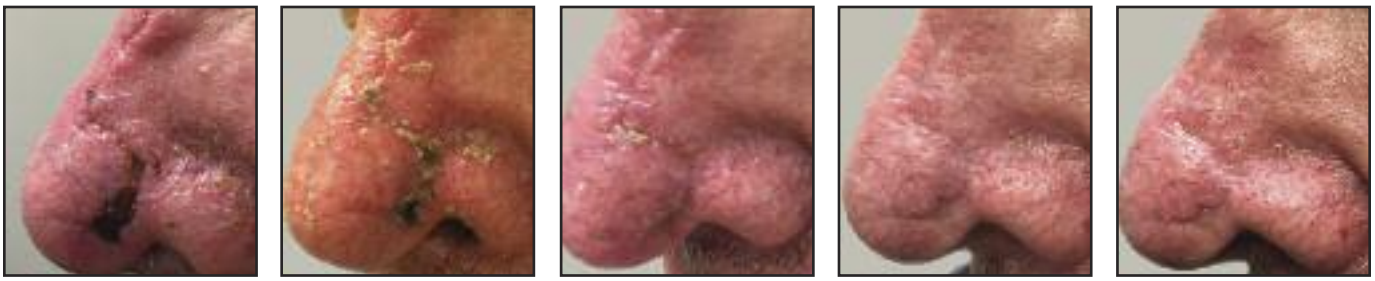

Figure 5. A linear and curved scar on the left nasal cavity of a 65-year-old man at baseline and at each return visit. The scar steadily improved until it is barely visible at 84 days.

improve the investigator-assessed parameters as shown by changes in VSS and OSAS scores, respectively, at each visit compared to baseline. The safety endpoint was the overall incidence of adverse events.

RESULTS

Fifteen subjects entered the study (mean age = 55.9±16.6 years; 4 females and 11 males). Subjects were all Caucasian, with the exception of a single African-American. All scars were linear following post-Mohs surgery (N=11) or post-excision of a benign lesion (N=4). All wounds had sutures and the test product was started after suture removal, which was seven days for the facial area and 14 days for areas off the face. One subject withdrew from the study after the baseline visit and was not included in the analyses. Another made all visits except at 84 days and this subject's data were included in all the analyses except at 84 days.

The Wilcoxon test was used to test for significant differences at each visit compared to baseline with $p<0.0125$ as the cutoff level to control for multiple comparisons with baseline. The efficacy endpoints were met for both the VSS and OSAS scores. The median total VSS score at each timepoint is shown in Figure 1. The reduction in score was statistically significant at

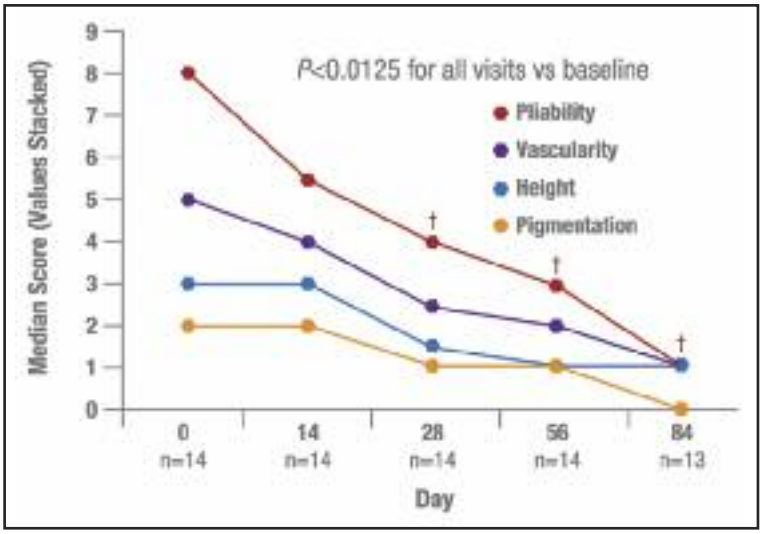

Figure 6. The stacked median Vancouver Scar Scale (VSS) score (n=14 for Days –56, n=13, for Day 84) for each VSS parameter at baseline and at each return visit. Individual median scores were stacked because the number of subjects per skin attribute is small. The reduction in VSS score at 84 days compared to baseline was significant for pliability (p=0.0020), vascularity (p=0.0020), height (p=0.0078), and pigmentation (p=0.0020).

each visit. Improvement of scars at specific anatomical locations is shown in Table 2 for each subject at 84 days. Most scars were located on the cheek (n=6), followed by the nose (n=4), temple (n=2), leg (n=1), and trunk (n=1). The improvement data (as % difference at 84 days from baseline) were not normally distributed by the Shapiro-Wilk Test (p=0.0042) so improvements were expressed in nonparametric statistics. The median improvement of the 14 subjects was 73.5 percent with an IQR = 15.9 percent. The IQR is the interquartile range, a measure of data dispersion.

The median total OSAS scores at each timepoint are shown in Figure 2. The reduction in score was significant at each visit. Adverse events were not observed during the study, fulfilling the safety endpoint. Clinical examples of subjects at each visit are presented in Figures 3, 4, and 5.

VSS evaluation parameters during the study are shown in Figure 6. The reduction in VSS score at 84 days compared to baseline was significant for each skin attribute.

The median OSAS score for vascularization compared to baseline decreased by 14 days and continued to decline steadily until 84 days. Median thickness scores declined steadily until 28 days where they levelled off for the remainder of the study. Median pigmentation scores showed a trend similar to that of vascularization.

P values for improvements compared to baseline for each individual parameter are shown in Table 3 for both median VSS and OSAS scores. For VSS parameters, significant differences from baseline began at 28 days for pliability and height, 56 days for vascularity, and 84 days for pigmentation. The OSAS individual parameters showed significant differences from baseline beginning at 14 days and continued until 84 days for vascularization, thickness, and pigmentation.

Pruritis was evaluated at each study visit (Figure 7). The median pruritis score was 2.5 at baseline, decreased to 2.0 at 14 days, and levelled off at 1.0 for the remainder of the study. Differences from baseline were significant at 56 days (p=0.0078) and at 84 days (p=0.0078).

Subject satisfaction was evaluated at the end of the study. Overall, 84.6 percent of subjects rated the treatment as excellent, very good, or good after three months of treatment.

DISCUSSION

International guidelines recommend the use of silicone gel for the prevention of excessive scarring after surgery or trauma and for the management of scars.[1,2,11,12] The purpose of the present study was to evaluate the efficacy and safety of a novel topical 100% silicone gel for early intervention in scar management. The test product is an advanced silicone treatment for minimizing the appearance of scars. The gel dries rapidly to form an invisible protective silicone sheet over the affected area. This protective

Table 3. Improvements compared to baseline for evaluation parameters of VSS and OSAS assessments

	P Value			
Scar Scale	**14 Days**	**28 Days**	**56 Days**	**84 Days**
VSS	—	—	—	—
Vascularity	0.0781 (ns)	0.2188 (ns)	0.0005 (s)	0.0020 (s)
Pliability	0.0273 (ns)	0.0068 (s)	0.0010 (s)	0.0020 (s)
Pigmentation	0.3125 (ns)	0.0742 (ns)	0.0547 (ns)	0.0020 (s)
Height	0.0625 (ns)	0.0078 (s)	0.0039 (s)	0.0078 (s)
OSAS	—	—	—	—
Vascularization	0.0068 (s)	0.0023 (s)	0.0004 (s)	0.0010 (s)
Thickness	0.0020 (s)	0.0010 (s)	0.0002 (s)	0.0005 (s)
Pigmentation	0.0122 (s)	0.0046 (s)	0.0001 (s)	0.0005 (s)

VSS=Vancouver Scar Scale; OSAS=Observer Scar Assessment Scale

barrier is flexible, waterproof, and breathable. The patented silicone gel formulation has been shown to flatten, soften, and smooth scars; relieve the itching and discomfort of scars; and reduce the discoloration associated with scars.

The VSS and OSAS total scores show that overall improvement of the appearance of the scars was significant as early as 14 days and improvement continued at least until 84 days with twice-daily use of test

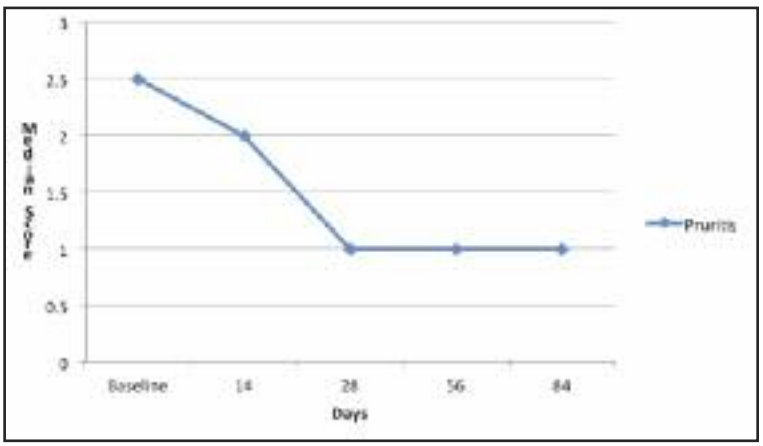

Figure 7. Median scores (1–10 scale) (n=14 for Days 0–56, n=13, for Day 84) for pruritis at baseline and at each return visit.

product (Figure 1). For VSS individual parameters, significant differences from baseline began at 28 days for pliability and height, 56 days for vascularity, and 84 days for pigmentation (Table 3). For OSAS parameters, significant differences from baseline began at 14 days and continued until 84 days for vascularization, thickness, and pigmentation (Table 3). Pain was minimal, and pruritis decreased with repeated twice-daily use of test product, leveling off at 1 from 28 to 84 days. Although the study did not take into account the subjects' assessments of their scars, subject satisfaction with the treatment was predominantly very good and no adverse events were observed in the study.

Another limitation is that this pilot study included a small number of subjects. Still, the encouraging results of the present study support the use of this novel 100% silicone gel in the early intervention for the management of scars.

CONCLUSION

The test product improved the appearance of scars after three months of treatment and with no adverse events.

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